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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,178	02/12/2002	David J. Eyre	7475-69889	5007
49437	7590	07/06/2005	EXAMINER	
ROCHE			SMITH, CAROLYN L	
11 SOUTH MERIDAN STREET			ART UNIT	
INDIANAPOLIS, IN 46204			PAPER NUMBER	

1631

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/074,178

Applicant(s)

EYRE ET AL.

Examiner

Carolyn L. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-24 is/are pending in the application.
4a) Of the above claim(s) 24 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 18-23 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 31 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission, filed 4/26/05, has been entered.

Amended claim 18, filed 4/26/05, are acknowledged.

Claims herein under examination are 18-23.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 (line 8) recites "a processor means" which is confusing as the originally filed application does not state how a "processor means" would differ from a processor. If applicants intend the "processor means" to be different from the "processor" mentioned in the specification, applicants must set forth these differences. Applicants are warned that any "processor means" intended for claim 18 must be specifically described in the specification, claims, or drawings, as

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originally filed, or it will be considered NEW MATTER. Clarification of this issue via clearer claim wording is requested. Claims 19-23 are also rejected due to their dependency from instant claim 18.

Claim 18 is confusing as it contains a "processor means" with method steps that follow without mention as to how these two concepts are interconnected. In the previous set of claims, Applicants recited "the processor is programmed to obtain" which clearly limited the processor to one programmed to perform the method steps. If Applicants intend the processor to be configured or programmed to perform certain method steps, this limitation must be set forth. Applicants are warned that wording involving the interconnection between the processor and method steps must be specifically described in the specification, claims, or drawings, as originally filed, or it will be considered NEW MATTER. Clarification of this issue via clearer claim wording is requested. Claims 19-23 are also rejected due to their dependency from instant claim 18.

Claim 18 recites the limitation "the processor" in line 9. There is insufficient antecedent basis for this limitation in the claim as there is no previous mention of a processor. Clarification of this issue via clearer claim wording is requested. Claims 19-23 are also rejected due to their dependency from instant claim 18.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 18-23 are rejected under 35 U.S.C. 102(a) and 102(e)(2) as being anticipated by Schork et al. (P/N 6,291,182 B1).

Schork et al. disclose methods, software, and apparatus for determining the presence of a gene with a detectable trait in a genomic region (presence of a nucleic acid in a sample) (abstract). Schork et al. disclose using a Perkin Elmer 9600 Thermocycler to perform amplification of nucleic acids (col. 47, lines 1-6). Schork et al. disclose performing 40 cycles with 30 seconds at 95 degrees Celsius, 1 minute at 54 degrees Celsius and 30 seconds at 72 degrees Celsius (col. 47, lines 2-6) which represent rapid thermal cycling, as stated in instant claim 22. Schork et al. disclose using a fluorimeter and Picogreen (fluorescence) to determine quantities of amplification products (col. 47, lines 7-9). Schork et al. disclose the use of dideoxy terminator sequencing reactions (col. 47, lines 10-15) which represent a plurality of tests. Schork et al. disclose determination of sequences of amplification products (processing data) wherein the sequence data is evaluated using software designed to detect sites among the

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amplified products via different fluorescent molecules and by evaluating intensity ratios (col. 47, lines 10-28) which represents processing data during amplification and obtaining scores based on the fluorescence which determines presence of amplified sequences, as stated in instant claim 18. Schork et al. disclose excluding artifacts due to background noise by comparing two DNA strands (col. 47, lines 29-34) which represents a signal-to-noise ratio test, as stated in instant claim 19. Schork et al. disclose using a variety of mathematic analysis tests, including Expectation-Maximization method (Maximum to Baseline Comparison Test) (col. 2, line 6), Wilcoxon rank test (function ordering test) (col. 2, line 62), Kolmogorov-Smirnov test (efficiency test using normal distribution) (col. 2, line 65), chi-square test (confidence interval test) (col. 2, line 50), and nonparametric tests (Last Rise Test) (Fig. 24), as stated in instant claims 20 and 21. Schork et al. disclose performing linkage analysis based upon establishing a correlation between transmission of genetic markers and that of a specific trait throughout generations within a family and statistical methods for determination of the likelihood that the marker and trait are segregating independently (col. 18, lines 39-64) which represents a type of Channel Consistency Test where the channel consistency is represented by the consistent flow (presence) or lack thereof of the marker and trait transmission throughout generations, as stated in instant claim 20.

Thus, Schork et al. anticipate the limitations in claims 18-23.

Applicants state that they have amended instant claim 18 to include “a processor means for processing data during the amplification” to clarify that a structural characteristic of the claimed device is that the processor is programmed to analyze data during amplification of the

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nucleic acids. This statement is unpersuasive as the recitation of being programmed to analyze data has been deleted from instant claim 18. It is noted that processing data and analyzing data are not the same. Furthermore, while method steps appear to be recited in the last 5 lines of instant claim 18, the claim no longer recites that the processor is programmed to perform these steps. It is recommended that Applicants thoroughly analyze the claim language to determine what they intend to be recited in instant claims. Applicants state that Schork et al. do not describe a processor that analyzes data during amplification of nucleic acids to ascertain whether the nucleic acid is present in the sample. This statement is not persuasive as the instant claims state "the processor means for processing data during the amplification" which is not the same as analyzing data. It is noted that any handling of data can be broadly and reasonably interpreted to represent a processing of data, regardless of whether or not it was analyzed. Applicants submit that the fluorimeter in Schork et al. detects fluorescence after amplification is complete. The broadest reasonable interpretation of the claim language "amplification of the nucleic acid" includes a broad process of amplification containing many steps which were never clearly defined by Applicants as to when it begins or ends. The end portion of this process includes the actual presence of amplified products which are then detected via fluorescence using a fluorimeter by Schork et al. Because the amplification process was not clearly defined by Applicants, it has been reasonably interpreted to include many steps, including steps involving amplified products. In addition, while the features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function (MPEP 2114). It is believed that the functional limitation of the fluorimeter "for detecting fluorescence during the amplification of the nucleic

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acid” is adequately disclosed by the Schork et al. fluorimeter for the reasons described above. It is further noted in Example 17 of the Schork et al. patent, PCR cycles were used with components containing fluorescent ddNTPs (col. 59, lines 18-37) which represents “fluorescence during the amplification of the nucleic acid” in yet another interpretation of this limitation in claim 18. Applicants summarize Schork et al. on column 47 and submit that the fluorescent measurement occurs after amplification. Again, it is noted that “during the amplification” can be recited broadly and reasonably as stated above to include many steps, including steps involving amplified products. It is also reiterated that “processing data” is broader in scope than analyzing data. Applicants state that it would be very clear to one skilled in the art that the phrase “during amplification” means only steps that occur during the polymerase chain reaction. This statement is found unpersuasive as there is not clear and concise definition of this phrase in the specification such that the Examiner is expected to interpret the phrase in its broadest and reasonable sense. Applicants mention phrases such as processing data and analyzing data during or after amplification. It is noted that these two verbs do not have similar scopes of interpretation. Applicants summarize Schork et al. and submit that Schork et al. do not disclose a processor means for processing data during the amplification of nucleic acids. This statement is found unpersuasive as any handling of data is considered to be a processing of data.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The

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faxing of such papers must conform to the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

June 23, 2005

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
6/30/05